K092563

510(k) Summary

NOV - 4 2009

Date Prepared: October 21, 2009

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Loucinda Bjorklund
Sr. Regulatory Affairs Associate
Tel: 763-656-4300; Fax: 763-656-4253
Email: lbjorklund@vascularsolutions.com

General Information

Trade Name	Gator™ ClipSeal Plug
Common / Usual Name	Hemostatic plug
Classification Name	870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting; Class II
Predicate Device	K073620 Guardian Hemostasis Valve (Zerusa Limited)

Device Description

The Gator ClipSeal Plug (GATOR) is a flexible polymer plug used to seal against blood loss through the hemostatic valve of 12F – 24F introducer sheaths. The GATOR can be used with 0.035" or 0.038" guidewires.

Intended Use / Indications

The Gator ClipSeal Plug is intended to be used with 12F to 24F introducer sheaths to maintain a hemostatic seal around 0.035" or 0.038" guidewires.

Substantial Equivalence and Summary of Studies

The Gator ClipSeal Plug is substantially equivalent in intended use and indications to the predicate device. Technological differences in design and materials have been qualified through biomaterial assessments and verification testing, the results of which did not raise any new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 4 2009

Vascular Solutions, Inc.
Ms. Loucinda Bjorklund
Sr. Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K092563
Vascular Solutions Gator ClipSeal Plug
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II
Product Code: DTL
Dated: August 19, 2009
Received: August 20, 2009

Dear Ms. Bjorklund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092563

Device Name: Gator™ ClipSeal Plug

Indications for Use:

The Gator ClipSeal Plug is intended to be used with 12F to 24F introducer sheaths to maintain a hemostatic seal around 0.035" or 0.038" guidewires.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092563